DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Jay Eltermann, Building 71, Room 6038 Telephone: (240) 402-9168 Industry Information: www.fda.gov/oc/industry	10/7-16/2020
	FEI NUMBER 3011834594

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Snehal Patel, Vice President, Site Head Bothell

FIRM NAME	STREET ADDRESS
Juno Therapeutics, Inc.	1522 217th Pl. SE
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bothell, WA. 98021	CAR-T Cell Therapy Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1.There is a failure to thoroughly review any unexplained discrepancy, the failure of a batch or any of its components to meet any of its specifications, whether or not the batch has been already distributed. Specifically,

DEV-2019-03442 (Critical Classification), created on 10Dec2019, reported a (b) (4) [redacted] DEV-2019-03442 Root Cause Analysis, Final Impact Analysis, and Corrective Actions were deficient for the following reasons.

a) The reliability of CoA from the vendor supplying (b) (4) Lots was not established and therefore the quality of previously supplied (b) (4) lots, which were released based on the vendor CoA (b) (4)) negative results, was not determined.

b) A clinical impact analysis was requested to understand the potential clinical risk of (b) (4) exposure to patients treated with (b) (4) where (b) (4) was used in the (b) (4) The clinical impact analysis stated there was no known transmission of (b) (4) to humans. The clinical impact analysis did not include an assessment of adverse events for patients treated with (b) (4) where (b) (4) was used in the (b) (4)

c) A CAPA with Effectiveness Checks, per SOP-001151, Global CAPA Management, dated 17Dec2018, was not opened specifically for DEV-2019-03442, to address the inconsistency between the OOS results from the contract testing lab for Juno Lot (b) (4) (Vendor Lot (b) (4)) and the vendor CoA negative (b) (4) results. CAPA

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Prabhu P. Raju, Investigator Eileen Liu, Investigator	10/16/2020

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effectiveness checks were not conducted for the implemented corrections involving the (b) (4) for the purpose of (b) (4), and the cleaning of QC/Microbiology locations where (b) (4) Juno Lot (b) (4) was used.

d) The contract test lab, that reported the positive (b) (4) result, conducted an OOS Investigation (Record ID: (b) (4) dated 07NOV2019) and concluded that the assay controls performed as expected and the assay is valid. The (b) (4) assay for (b) (4) was positive from the contract laboratory that tested (b) (4) (b) (4) Lot (b) (4) and negative from the vendor that supplied (b) (4) Lot (b) (4) DEV-2019-03442 did not include an OOS investigation conducted by the (b) (4) vendor (Material Supplier), as per Attachment C (GMP Material Supplier Investigations) of the Global Deviation SOP, SOP-001145, dated 07Jun2019, to determine if their assay produced a valid result, and the assay controls performed as expected.

2. Written records of investigations into unexplained discrepancies, the failure of a batch or any of its components to meet specifications, do not always include the appropriate conclusions and follow-up. The following Notice of Events (NOEs) were not classified as Deviations.

a) DEV-2020-02527, dated August 29, 2020, NOE Classification, reported Suspected (b) (4) during (b) (4) of Lot (b) (4). The Deviation was classified NOE only since there was no impact to product. The (b) (4) Material ((b) (4) Lot (b) (4), had a (b) (4) . (b) (4) typically has a (b) (4) SOP-000236, (b) (4) Response, dated 02Apr2020, requires a deviation be initiated in the event of suspected (b) (4)

b) DEV-2020-02599, dated September 4, 2020, NOE Classification, reported (b) (4) Pipette (b) (4) Found to be Out of Process Tolerance During On Demand Calibration. This Event was classified NOE only since there was no impact to product quality. However, the Description section of this deviation stated the potential impact from out of tolerance pipettes would result in invalid test results and failure to meet assay and sample acceptance criteria. Approximately (b) (4) lots had invalid test results and were identified as lots that were potentially affected by the pipettes out of tolerance failure.

c) DEV-2020-02726, dated September 17, 2020, NOE Classification, reported Operators inadvertently (b) (4) during for Lot The cause was determined to be

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Personnel Inattention and DEV-2020-02726 was classified NOE-only. Management counseling of the manufacturing operators was completed but a CAPA, per SOP-00151 (Global CAPA Management, dated 17Dec2018), with Effectiveness Checks for the management counseling corrective action was not implemented.

3. The written procedure for Manufacturing Material Visual Inspection, SOP-000512, dated 20Jun2020, defines the method used to inspect raw, intermediate, and Formulated Drug Product (FDP) materials for foreign particulates and defects, and applies to the visual inspection of GMP materials used throughout the manufacturing process. SOP-000512 does not specify when in the manufacturing process (b) (4) intermediate materials, (b) (4), and their immediate containers are inspected for (b) (4) Specifically,

a) (b) (4)

b) (b) (4)

4. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established or followed. Specifically,

On 10/08/2020, we observed the aseptic filling of drug product (DP) Lot (b) (4) (b) (4) the ISO (b) (4) (b) (4)) in the (b) (4), Rm (b) (4) We observed the following deficient aseptic practice.

a) We observed an aseptic verifier (b) (4) his gloves with sterile (b) (4) before performing personnel monitoring (PM) of his gloves. SOP-000567, entitled "ISO (b) (4) Environmental Monitoring and ISO (b) (4) Personnel Monitoring", V10.0, section 15.2 states (b) (4)

b) We also observed an aseptic operator performing viable surface monitoring of the (b) (4) For each sample

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collected, the operator (b) (4) . After completing the surface monitoring, he proceeded to perform PM of his gloves. SOP-000567, entitled "ISO (b) (4) Environmental Monitoring and ISO (b) (4) Personnel Monitoring", V10.0, section 13.6 states (b) (4)

5. Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity. Specifically,

a) MET-000054, entitled "Bacterial Endotoxin Test Method", V8.0 is deficient in that it fails to specify the minimum time required for the adequate (b) (4)

b) On 10/13/2020, we observed (b) (4) DP lots (b) (4) assessments in the Analytical Chemistry Rm (b) (4) We observed the analyst did not (b) (4) reference standards for (b) (4) assessment, she also did not (b) (4) test sample for (b) (4) assessment. MET-001013, entitled "Appearance by Visual Inspection", V6.0, section 11.6 states (b) (4) . Additionally, section 11.7.1 states to (b) (4) (b) (4)

6. Deviations from written test procedures are not justified to assure compliance with established specifications and standards.

On 10/07/2020 in the Environmental Monitoring Laboratory Rm (b) (4) we randomly selected and inspected EM plates that had been enumerated, counts verified by a second verifier, and results recorded in LIMS earlier the same day. We observed (b) (4) of the inspected EM plates showed discrepant enumeration results. The observed discrepancies were confirmed by the firm's management.

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		Prabhu P. Raju, Investigator Eileen Liu, Investigator	10/16/2020

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.

Seattle District (SEA-DO),
22215 26th Ave SE, Suite 210,
Bothell, WA 98021 Phone: (425) 302-0340

TO

2. NAME AND TITLE OF INDIVIDUAL
Mr. Jeffrey L. Masten, Vice President Quality Assurance

3. DATE
10/07/2020

4. FIRM NAME
Juno Therapeutics, Inc.

5. HOUR
8:50 (a.m.) p.m.

6. NUMBER AND STREET
1522 217th Pl. SE

7. CITY AND STATE & ZIP CODE
Bothell, WA. 98021

8. PHONE NO. & AREA CODE
(206) 829-3711

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
	Prabhu P. Raju, Investigator
	Eileen Liu, Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

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Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."